

HOUSE BILL 684
By Overbey

AN ACT to amend Tennessee Code Annotated, Title 68,
relative to medical research.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF TENNESSEE:

SECTION 1. Tennessee Code Annotated, Title 68, is amended by creating a new chapter designated as Chapter 58 relative to medical research involving human subjects, and by inserting the following as a new section thereto:

(a) No health care facility licensed or regulated by the department pursuant to this title shall conduct a clinical trial involving any pharmaceuticals unless the health care facility obtains the written agreement of all parties involved in the clinical trial, including the pharmaceutical company or companies involved, that the results of the clinical trial shall be released to the public, and that the research shall be registered with the National Institutes of Health on the Internet website clinicaltrials.gov or any successor website operated by the National Institutes of Health for that purpose. The health care facility shall be responsible for obtaining this agreement.

(b) The health care facility shall release the information to the public by producing a summary of the results of the clinical trial within a reasonable time not to exceed three (3) months following the completion of the compilation and study of the clinical trial data. The summary must be approved by the health care facility's institutional review board. The summary shall be made available upon request to the public, or shall be made available on the health care facility's Internet website, if any. If the health care facility chooses to make the summary available upon request to the public, the health care facility may charge the requestor a reasonable administrative fee not to exceed the maximum fee for copying medical records of the same length as the

summary. The summary shall comply with all applicable federal and state laws regarding the confidentiality of individually identifiable information about research subjects.

(c) Failure to comply with this section shall be grounds for discipline of the health care facility conducting the clinical trial, pursuant to title 68, chapter 11.

(d) This section shall not apply to any clinical trial that was initiated prior to July 1, 2005, but shall apply to any clinical trial initiated on or after July 1, 2005.

SECTION 2. This act shall take effect upon becoming a law, the public welfare requiring it.